1 2 3 4 5 6 7	NEWPORT TRIAL GROUP A Professional Corporation Scott J. Ferrell, Bar No. 202091 sferrell@trialnewport.com David W. Reid, Bar No. 267382 dreid@trialnewport.com 610 Newport Center Drive, Suite 700 Newport Beach, CA 92660 Tel: (949) 706-6464 Fax: (949) 706-6469				
8	Attorneys for Plaintiff				
9	LINITED OT ATEC 1	DISTRICT COURT			
10	UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA				
11	SOUTHERN DISTRIC	CT OF CALIFORNIA			
12 13 14 15	UNITED STATES OF AMERICA, Ex. Rel., ZACHARY HALLSTROM, Plaintiff,	Case No. <u>'10CV2492 WQHRBB</u> COMPLAINT FOR FALSE PATENT			
16	VS.	MARKING			
17 18 19 20 21	ULTIMATE NUTRITION, INC.; and DOES 1-10, Inclusive, Defendants.	JURY TRIAL DEMANDED			
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23	I. <u>INTRODUCTION</u>				
24	1. This lawsuit is brought to stop sophisticated Defendants from luring				
25	vulnerable consumers into paying an outrageous price for a worthless dietary				
26	supplement – namely, Ultimate Nutrition's "Bulgarian Tribulus" ("Tribulus") – by				
27	falsely claiming that the product is patented (it is not). Based upon Defendants'				
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- 2. The false claims regarding Tribulus's patent rights have misled consumers into paying an outrageous price for Tribulus, have stifled innovation by discouraging research and development of competing products, and have injured the general public by distorting the marketplace.
- 3. Plaintiff therefore brings this action to stop Defendants' deception and hold them accountable for the applicable monetary penalties resulting from their false patent marking under 35 U.S.C § 292.

II. JURISDICTION, VENUE, AND STANDING

- 4. This Court has subject matter jurisdiction pursuant to 35 U.S.C. §292(b) and 28 U.S.C. § 1338(a).
- 5. Defendants are subject to personal jurisdiction in this District because they conduct business in this district and the exercise of jurisdiction over them would not offend traditional notions of fair play and substantial justice.
- 6. Venue is proper in this District under 28 U.S.C. §§1391(c) and 1395(a), because Defendants' products that are the subject of this Complaint are advertised for sale, offered for sale, and sold within this judicial district.
- 7. Plaintiff possesses the requisite standing required by Article III of the United States Constitution pursuant to 35 U.S.C. §292(b), which confers upon any person the right to sue for civil monetary penalties, restitution, and injunctive relief for false patent marking.

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III. THE PARTIES

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The Plaintiff

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8. Plaintiff, ZACHARY HALLSTROM, is a California citizen who believes in the importance of a fair and competitive market for the manufacture, marketing, sale, and distribution of consumer products.

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В. The Defendants

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- Defendant ULTIMATE NUTRITION, INC. is a Connecticut corporation 9. doing business throughout the United States that owns, advertises, and distributes the Tribulus brand of dietary supplements.
- 10. Plaintiffs do not know the true names or capacities of the persons or entities sued herein as DOES 1 to 10, inclusive, and therefore sue such Defendants by such fictitious names. Plaintiffs will amend this complaint to set forth the true names and capacities of these Defendants when they have been ascertained.

IV. BACKGROUND FACTS

The Purpose of this Action

11. The purpose of this lawsuit is to act in the public interest to enforce the policy underlying the false marking statute, 35 U.S.C. §292.

B. The Policy of the Patent Marking Statute

- The patent marking statute (35 U.S.C. §287 and the false patent marking 12. statute (35 U.S.C. §292) exist to ensure that the public has accurate information regarding the existence, scope, and nature of patent rights.
- 13. The purposes of the patent marking statute were explained by the Federal Circuit in Nike, Inc. v. Wal-Mart Stores, Inc., 138 F.3d 1437, 1443 (Fed. Cir. 1998), as: (1) helping to avoid innocent infringement, (2) encouraging patentees to give notice to

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the public that the article is patented, and (3) aiding the public to identify whether an article is patented.

14. Over half a century ago, the Supreme Court stated in *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery*, 324 U.S. 806, 816 (1945), that patents by their very nature are affected with a public interest:

The possession and assertion of patent rights are 'issues of great moment to the public.' A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts.' At the same time, a patent is an exception to the general rule against monopolies and to the right to access to a free and open market.

- 15. The Patent Act of 1952 provides a *qui tam* cause of action on behalf of the public to fine the offender in an amount of up to \$500 for each falsely marked article, with half of any recovery paid to the United States government and half of any recovery paid to the plaintiff bringing the action.
- 16. False marking of unpatented articles as "patented" is injurious to the public Interest in at least the following ways:
 - Acts of false marking deter innovation and stifle competition in the marketplace.
 - False marks deter scientific research when an inventor sees a mark and decides to forgo continued research to avoid possible infringement.
 - False marking can cause unnecessary investment in design around or costs incurred to analyze the validity or enforceability of a patent whose number has been marked upon a product with which a competitor would like to compete.

Additionally, consumers who see a product as "patented" are likely to infer the product possesses design or utilitarian features that are unique to such article, and not available in substitute articles from other producers, thus inducing consumer demand for the marked article and causing consumers to pay an artificial premium for the product.

Defendants' False Marking in Violation of the Patent Act C.

- Defendant Ultimate Nutrition, Inc. manufactures, advertises, licenses, and 17. distributes the Tribulus brand of dietary supplements.
- 18. The product packaging boldly declares that Tribulus is patented. Based upon the false assertion that the product is patented, Defendants advertise and sell Tribulus to the public as a purported way to increase testosterone and sex drive. Each bottle of Tribulus contains 90 capsules that are ingested orally. Defendant Ultimate Nutrition, Inc. advertises Tribulus as a,

"potent supplement that allows the body to naturally increase testosterone, possibly allowing for greater muscle growth and increased strength and stamina ... Studies show that it also works very well for increasing sex drive!" (See Exhibit 1.)

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The following picture of the Tribulus packaging has been widely 19. disseminated by the Defendants:



(See Exhibit 2 for full product label.)

- 20. As evidenced by the above photo, each and every bottle of Tribulus is marked with the word, "Patented." The false marking is outlined in red and is central to the product packaging design. Defendant Ultimate Nutrition, Inc. sells Tribulus on GNC's website. GNC's website provides the following United States Patent number: 6,343,258. (See Exhibit 3.)
- 21. In reality, Tribulus is **not** patented—at least not the Tribulus that Defendants market and distribute. Counsel for Plaintiff has exhaustedly researched public records, including the records of the United States Patent & Trademark office (found at www.uspto.gov) that are presumed to be conclusively accurate, and have

confirmed that the pill-form Tribulus manufactured, marketed and distributed by Defendants is *not* covered by U.S. Patent No. 6,343,258.

- 22. While U.S. Patent No. 6,343,258 is indeed a patent number that relates to tribulus, the patent only covers "a cream made from the herb Tribulus Terrestris L for topical use" that is used to treat things like "vulvo-vaginitis, vulvo-hemorrhoids, varicose veins, and acne." (emphasis added) (See Exhibit 4.) There are three main problems with Defendants' U.S. Patent No. 6,343,258 claim: 1) Defendants market and distribute Tribulus in pill form (not the patent-covered cream form); 2) Defendants' Tribulus is ingested (not applied topically like the patent-covered cream); and 3) Defendants' market Tribulus as a way to increase testosterone and sex drive (not to treat vulvo-vaginitis, vulvo-hemorroids, varicose veins, and acne as the patent-covered cream does).
- 23. Indeed, U.S. Patent No. 6,343,258 describes a completely different product than Defendants' Tribulus. The product Defendants mark and advertise as patented is simply not patented. Defendants have falsely marked Tribulus as patented and have done so intentionally to deceive the public and increase sales by inducing consumers to purchase their product over competitive products that are not marked as patented. Defendants are well aware that their product is not covered under U.S. Patent No. 6,343,258, but they were hoping that the public would not discover that the tribulus terrestris 1 described in U.S. Patent No. 6,343,258 is categorically different than Defendants' product shown above in paragraph 20. As of the date of this Complaint, Defendants continue to falsely mark and advertise Tribulus as patented.
- 24. Given that one of the reasons plaintiff purchased the product was because he believed it to be proprietary, he was obviously not satisfied with his purchase and suffered a competitive injury thereby.

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D. Defendants' Violation of the Patent Act Was Intentional.

- 25. This case is "exceptional" for purposes of 35 U.S.C. § 285 because Defendant Ultimate Nutrition, Inc. had no reasonable basis upon which to genuinely believe that Tribulus was patented. Moreover, the Defendants knew that U.S. Patent No. 6,343,258 refers to a topical lotion, containing tribulus terrestris 1, which is used to treat various skin conditions and *not* their Tribulus product.
- 26. In fact, Defendants are no strangers to false claims associated with the marketing of Tribulus. Defendants' own claims as to the efficacy of Tribulus to increase testosterone levels have been discredited by numerous independent studies. Defendants claim that Tribulus will "increase testosterone" by "increasing luteinizing hormones" which lead to "increasing sex drive!" (See Exhibit 1.) However, independent studies have shown that these statements are misleading at best. One such study states that there is "little if any data supporting the erogenic value of tribulus terrestris supplementation ... with some potentially dangerous side effects." (See Exhibit 5.) Another found that tribulus had "no effect on the body composition or exercise performance." (See Exhibit 6.) Defendants employ the same deceptive and misleading marketing tactics with their false patent claim.
- 27. This false marking scheme has deceived the public and stifled legitimate competition, allowing Defendants to gain a competitive advantage in the market, where there are now several competing products available for a lower price.

V. FIRST CAUSE OF ACTION: FALSE PATENT MARKING

- 28. Plaintiff re-alleges the preceding paragraphs and incorporates them herein by reference.
- 29. Defendants know that they can charge a premium for dietary supplements that the public perceives to be unique and protected by a patent.
- 30. Defendants have continuously advertised on each bottle of Tribulus that it is patented and have sold Tribulus as patented when it is not.

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31. Defendants have violated 35 U.S.C. § 292(a), which provides in relevant part:

Whoever without the consent of the patentee, marks upon, or affixes to, or uses in advertising in connection with anything made, used, offered for sale, or sold by such person within the United States, or imported by the person into the United States, the name or any imitation of the name of the patentee, the patent number, or the words "patent," "patentee," or the like, with the intent of counterfeiting or imitating the mark of the patentee, or of deceiving the public and inducing them to believe that the thing was made, offered for sale, sold, or imported into the United States by or with the consent of the patentee; or Whoever marks upon, or affixes to, or uses in advertising in connection with any unpatented article the word "patent" or any word or number importing the same is patented, for the purpose of deceiving the public; or Whoever marks upon, or affixes to, or uses in advertising in connection with any article the words "patent applied for," "patent pending," or any word importing that an application for patent has been made, when no application for patent has been made, or if made, is not pending, for the purpose of deceiving the public - Shall be fined not more than \$500 for every such offense.

- 32. Each false marking on or advertising of a bottle of Tribulus has misled consumers about their options regarding dietary supplements and has stifled research into and development of competing products. As such, Defendants' actions have harmed the public, its competitors, and the United States.
- 33. Defendants have wrongfully and illegally advertised a patent monopoly that they do not possess and, as a result, have benefitted commercially and financially by maintaining false statements of patent rights and by selling products that are falsely marked as such.

1 Defendants are therefore liable to plaintiff and to the United States under 34. 2 35 U.S.C. §292 (b). The public interest requires that Defendants be enjoined from 3 further acts of false marking, pay civil penalties, and make restitution for their ill-gotten 4 gains. 5 6 PRAYER FOR RELIEF VI. 7 Plaintiff seeks entry of judgment against Defendants as follows: 8 A judicial determination that Defendants have violated 35 U.S.C. §292 by 9 falsely advertising and marking Tribulus as "patented" for the purpose of deceiving the 10 public; 11 2. An order fining Defendants for false marking in an amount that is 12 reasonable in light of the total revenue and gross profit derived from the sale of falsely 13 marked bottles of Tribulus and the degree of intent to falsely mark which is proven, 14 with half of the fine paid to the United States Government and the other half to plaintiff; 15 3. An order preliminarily and permanently enjoining Defendants from 16 committing new acts of false patent marking and to cease all existing acts of false patent 17 marking; 18 An award of attorneys' fees and costs incurred in bringing and maintaining 4. 19 this action as to Defendant Ultimate Nutrition, Inc. in part because the case is 20 "exceptional" for purposes of the Patent Act; and 21 /// 22 /// 23 /// 24 /// 25 ///

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1	5. Any such other relief to which plaintiff, the United States, or the general public		
2	2 may be entitled.		
3 4 5	Dated: December 3, 2010 NEWI A Pro-	PORT TRIAL GROUP Sessional Corporation	
6		/s/ Scott J. Ferrell	
7	By	ott J. Ferrell	
8	8 Attorn	eys for Plaintiff	
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1	<u>DEMAN</u>	D FOR JURY TRIAL
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3	Pursuant to Federal Rule of C	Civil Procedure Section 38(b), Plaintiff demands a
4	trial by jury on all issues so triable.	
5	Data de Danamban 2, 2010	NEWDORT TRIAL CROUD
6	Dated: December 3, 2010	NEWPORT TRIAL GROUP A Professional Corporation
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8		By: /s/ Scott I Forvall
9		By: /s/ Scott J. Ferrell Scott J. Ferrell
10		Attorneys for Plaintiff
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December 3, 2010

PRODUCT SEARCH





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ULTIMATE NUTRITION BULGARIAN TRIBULUS Benefits of a natural testosterone enhancer ULTIMATE NUTRITION

Tribulus Terrestris available in:

90 count Capsules (750 mg.) View Supplement/Nutrition Facts

Tribulus terrestris is a plant that grows in many tropical and moderate areas of the world. Many different cultures have used it for a number of benefits. Studies have shown it to be a potent supplement that allows the body to naturally increase testosterone, possibly allowing for greater muscle growth and increased strength and stamina.

Studies show that it also works very well for increasing sex drive! It increases testosterone levels in a different way, however, than DHEA. Instead of being a testosterone precursor, tribulus leads to the production of the luteinizing hormone (LH). When LH levels are increased, the natural production of testosterone also increases. LH is a hormone that also deals with sex drive.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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EXHIBIT 1 13

(Tribulus Terrestris L.). Naturally contains over 45% steroidal

Each Capsule Contains: 100% Bulgarian Tribulus 750 mg

Amount per serving: 1 Capsule

Septement Facts

Farmington, CT 06032 USA Ultimate Nutrition Inc.

Distributed by: 750mg* 0046 dicalcium phosphate and magnesium stearate. Other ingredients: Gelatin, cellulose, 907 Servings per container: 90 * Daily Value not established Amount per serving fribulus (fruit) PLATINUM SERIES **750mg** Herb Supplement g 90 Capsules intended to diagnose, treat, cure or prevent any disease. Bulgarian state standard specification #0N 0273062-81 saponins, United States Patent No. 6,343,258. Meets condition or pregnant or lactating women. Suggested use: As a dietary supplement, These statements have not been evaluated by the Food and Drug Administration, This product is not for use by those with a serious medical Warning: This product is not intended • Tamper Resistant: Do not use if seal Consult your physician before use. under cap is broken or missing. take one or two capsules daily. Keep out of reach of children. Store in a cool dry place.

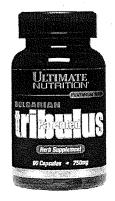
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Free Shipping on Orders of \$99 or Morel Details

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QTY: 1

AVAILABILITY: In stock, Ships in 1-2 full bus, days. Details

No Payments! #BillMeLater + No Interest if paid in full in 6 Months On orders over \$250. Subject to credit approval, See Terms

DESCRIPTION

SUPPLEMENT FACTS

LABEL

RATINGS AND REVIEWS

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Q & A

ULTIMATE NUTRITION®

Bulgarian Tribulus Patented capsules Dietary Supplement Each Capsule Contains: 100% Bulgarian Tribulus......750 mg (Tribulus Terrestris L.)

Naturally contains over 45%steroidal saponins.

Unites States Patent No. 6,343,258

Meets Bulgarian state standard specification #ON 0273062-81 * These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat. cure, or prevent any disease.

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PEOPLE WHO BUY THIS ITEM ALSO

Now® Sports Tribulus 90 Tablets



Price: \$19.99



With Gold Card Purchase: \$15.99



Life Extension® DNA Protection Formula 60 Vegetarian Capsules

Price: \$28.00

With Gold Card Purchase: \$22,40

Now® Sports ZMA® 90 Capsules

Price: \$19.99

With Gold Card Purchase; \$15.99

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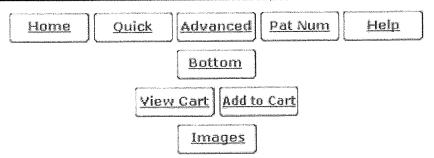
Maximum Human Performance TRAC® Extreme-NO - Orange 27 oz(s)

Price: \$49.99

With Gold Card Purchase: \$39.99

EXHIBIT 3

USPTO PATENT FULL-TEXT AND IMAGE DATABASE



(1 of 1)

United States Patent

6,343,258

Alexis January 29, 2002

Method for testing for readiness for harvesting of tribulus terrestris l. having high steroidal saponin content

Abstract

A cream made from the herb Tribulus Terrestris L. The cream preparation is made by low temperature water/alcohol extraction of Tribulus Terrestris L. After water/alcohol extraction of the herb Tribulus Terrestris L the extract is concentrated with a vacuum evaporator and mixed with a cream to concentrations of about 5, 10, 15% based on raw starting material. A number of factors are critical in preparation of the Tribulus Terrestris L raw material. These include: time of harvesting, part of the herb used, specific geographic area in Bulgaria where the herb is gathered, method of harvesting, and low temperature drying. Adherence to these factors guarantees high steroidal saponin, sapogenin and sterol content of the raw material used for making the cream. The finished cream has very strong antibacterial, anti-inflammation, anti-virus, anti-herpes effect and has been found to be highly useful in treating vulvo-vaginitis, vulvo-hemorrhoids, varicose veins and acne with. In some cases it blocks cancer cells from growing. This product was also found to be very successful in suppository form for the treatment of vulvo-vaginal, vulvo-hemorrhoidal and colonic conditions.

Inventors: Alexis; Brian (Santa Monica, CA)

Appl. No.: 09/373,812

Filed: **August 13, 1999**

Current U.S. Class:

702/23; 424/725; 702/22; 702/30

Current International Class:

A01N 65/00 (20060101); G01N 31/00 (20060101); G06F 19/00 (20060101); A61K 39/385 (20060101); A61P

15/00 (20060101); A61P 15/02 (20060101); G01N 031/00 ();

G06F 019/00 (); A01N 065/00 (); A61K 035/78 ()

Field of Search:

424/191.1,725 702/22,23,30

References Cited [Referenced By]

U.S. Patent Documents

 4774229
 September 1988
 Jordan

 5607693
 March 1997
 Bonte et al.

Foreign Patent Documents

403190809 Aug., 1991 JP

Other References

Gupta et al. Review On Phytochemical And Pharmacological Aspects Of Tribulus Terrerstris Linn Indian Drugs 34(B) pp. 422-424, Feb. 22, 1997.* . Hoffman, D. The Herbal Handbook pp. 201-211, 1987..

Primary Examiner: Weber; Jon P. Assistant Examiner: Patton; Patricia

Attorney, Agent or Firm: Cislo & Thomas LLP

Claims

What is claimed is:

- 1. A method for testing for readiness of harvesting of Tribulus terrestris L. comprising:
- a. mixing an approximately 500 mg sample of Tribulus terrestris L. with approximately 200 ml of deionized water to create a mixture;
- b. bending the mixture for about fifteen minutes in a container with sufficient speed to create a vortex;
- c. immediately examining the level of foam and water in the container, and
- d. if there is at least 1.5 times as much foam as water, harvesting the entire crop of Tribulus Terrestris L. within the week, otherwise repeating steps (a) through (d) until there is at least 1.5 times as much foam as water.
- 2. The method of claim 1, wherein the sample of Tribulus terrestris L. consists essentially of leaves, fruits and stems.
- 3. A method of testing for readiness of harvesting of Tribulus terrestris L. comprising the steps of:
- a. collecting a 500 mg sample of leaves fruit and stems of Tribulus terrestris L.;
- b. adding about 200 ml deionized water;
- c. blending for about 15 minutes in a blender with sufficient speed to create a substantial vortex;
- d. immediately examining the level of foam and water in the blender; and
- e. if there is at least 1.5 times as much foam as water, harvesting the entire crop of Tribulus Terrestris L

within the week, otherwise repeating steps a. through e. until there is at least 1.5 times as much foam as water.

- 4. The method of claim 3 wherein the sample of Tribulus Terrestris L. leaves, fruits and stems is dried at approximately 45.degree. C. prior to performing step (a).
- 5. The method of claim 3 wherein the Tribulus Terrestris L. is harvested from southern Bulgaria.
- 6. The method of claim 3 wherein the Tribulus Terrestris L is harvested from southern Bulgaria between approximately July first and August 15.
- 7. The method of claim 6 wherein the Tribulus Terrestris L is harvested from southern Bulgaria between approximately July first and July thirtieth.

Description

BACKGROUND OF THE INVENTION

The present invention relates to the field of therapeutic compounds for the treatment of diseases of the skin. In particular the present invention relates to creams made from the herb Tribulus Terrestris which are useful in the treatment of vulvo-vaginitis, vulvohemorrhoids, varicose veins and acne.

Tribulus Terrestris, commonly known as "Puncture Vine" or Caltrop fruit, is an herb that has been used for centuries in Europe for hormone insufficiency in men and women. It has also been used in the treatment of liver, kidney and urinary tract disease, and all types of skin disorders by Chinese herbalists for over 400 years.

In recent years Tribulus Terrestris has been touted as a dietary supplement for improving athletic performance. It has been discovered that ingestion of Tribulus Terrestris significantly elevates the level of several hormones: Testosterone; Luteinizing Hormone; Follicle Stimulating Hormone; and Estradiol. Clinical studies on Tribulus, conducted at the Chemical Pharmaceutical Institute in Sofia, Bulgaria, showed improved reproductive functions, including increased sperm production and Testosterone levels in men. Among women, Tribulus Terrestris increased the concentration of hormones including Estradiol, with Testosterone being very slightly influenced, thereby improving reproductive function, libido and ovulation. The active components of Tribulus Terrestris have a stimulating effect on the immune, sexual and reproductive systems, leading to improved muscle building, stamina and endurance. Other positive changes observed in a number of cases were a reduction in cholesterol, enhanced mood and well-being. No adverse effects to the central nervous or cardiovascular systems were noted in any of the clinical studies.

However, to date, no one has realized that a cream made from Tribulus Terrestris might have a very strong anti-bacterial, anti-inflammation, anti-virus, anti-herpes effect and be highly effective for treatment of vulvo-vaginitis, vulvo-hemorrhoids, varicose veins and acne.

Development of a cream made from Tribulus Terrestris which has a very strong anti-bacterial, anti-inflammation, anti-virus, anti-herpes effect represents a great improvement in the fields of dermatology and gynecology and satisfies a long felt need of dermatologists and gynecologists.

SUMMARY OF THE INVENTION

12/3/2010

The present invention is a cream made from the herb Tribulus Terrestris L for topical use. It has very strong anti-bacterial, anti-inflammation, anti-virus, anti-herpes effect and has been found to be highly useful in treating vulvo-vaginitis, vulvo-hemorrhoids, varicose veins and acne with. In some cases it blocks cancer cells from growing.

The cream preparation is made by low temperature water/alcohol extraction of Tribulus Terrestris L. A number of factors are critical in preparation of the Tribulus Terrestris L raw material. These include: time of harvesting, part of the herb used, specific geographic area in Bulgaria where the herb is gathered, method of harvesting, and low temperature drying. Adherence to these factors guarantees high steroidal saponin, sapogenin and sterol content of the raw material used for making the cream.

After water/alcohol extraction of the herb Tribulus Terrestris L the extract is concentrated with a vacuum evaporator and mixed with a cream to concentrations of about 5, 10, 15% based on raw starting material. This product was also found to be very successful in suppository form for the treatment of vulvo-vaginal, vulvo-hemorrhoidal and colonic conditions.

An appreciation of the other aims and objectives of the present invention and an understanding of it may be achieved by referring to the accompanying drawings and description of a preferred embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

- FIG. 1 is a graph showing the importance of vulvo-vaginitis symptoms.
- FIG. 2 is a graph showing how various symptoms improve with treatment.
- FIG. 3 is a chart of the data used in preparation of FIG. 2.
- FIG. 4 is a graph showing improvement in various symptoms.
- FIG. 5 is a bar chart showing physician assessment of results of treatment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Method of Harvesting the Herb Tribulus Terrestris L

- 1. The herb Tribulus Terrestris L is harvested from the southern part of Bulgaria where high concentration of steroidal saponins, sapogenins and sterols in the herb has been confirmed by years of analysis.
- 2. The parts of the herb Tribulus Terrestris L used are: leaves, fruits and stems.
- 3. Method for quick analysis of steroidal saponins, sapogenins and sterols:

Take 500 mg. from the harvested and dried (at a temperature of 45.degree. C.) plant material (leaves, fruits, and stems) of Tribulus Terrestris L.

Blend for 15 minutes in a blender with 200 ml. water. If the white foam level of the saponins is 1.5 times higher than the water level, the plant is ready for harvesting.

Once activity of steroidal saponins is confirmed, the harvesting process must be finished within one

week.

Time of harvesting in Bulgaria is usually between July 1-July 30 and, depending on the weather conditions, as late as August 15.

- 4. Once the plant has been harvested it must be stored in a dry place or dried immediately.
- 5. Drying of the herb must be done at a low temperature (40.degree. C.) in an oven or at room temperature in a dry, very well ventilated facility. In order to keep the activity of the steroidal saponins in the raw material high the moisture content has to be less than 10%.

Extraction Method of the Herb Tribulus Terrestris L

Extraction is done with a blender. Prior to blending, a high speed shredder and mixer pulverizes the tissues thereby completely releasing the steroidal saponins and sapogenins from the herb. The size of the cuts is 0.1 mm to 10 mm. A mixture of leaves, fruit and stems is used.

EXAMPLE

Shred a mixture of leaves, fruit and stems of Tribulus Terrestris to a size of 0.1 to 10 mm in a shredder. For each 1 g of mixture, add about 300 ml deionized (DI) water and extract for about 15 min in a blender. Sufficient speed should be used to create a substantial vortex. Add about 150 ml ethyl alcohol, mix, leave for 48 hours and then filter. Distill off the ethyl alcohol then concentrate the water extract with a vacuum evaporator to about 1 ml for each g of starting mixture. Finally, mix with a cream base to a concentration of 5% and 7.5% Tribulus Terrestris L concentrated water extract. Any cream base used for dermatological uses can be used. Alternatively, mix with glycerin or paraffin to make into a suppository form.

Testing of Creams

Creams made as described above with 5% and 7.5% Tribulus Terrestris L concentrated water extract were used for local treatment in 275 women with vulvo-vaginitis. A physician carried out the treatment after obtaining samples from the vagina, cervix and vulva. In most cases the condition was classified as candidiasis. Application of the creams was done after the confirmation of the diagnosis through microbiological testing. Quick improvement of the symptoms of the vulva was noted even on the first day of the application of the cream.

The treatment had very good acceptance according to the opinion of the patients as well as their physicians. Vaginal antiseptic creams are preparations for treatment of local problems of the vulva in the region of the vulvo-vagina. The epithelia of the vagina is an effective barrier against infection, however, at the same time it is a propitious environment for the development of protective flora and can permit development of numerous pathogenic microorganisms. These vaginal antiseptic creams are used for the treatment of vulvo-vaginitis through their action on the genital mucosa as a skin disinfectant.

Efficacy in addition to good acceptance in one delicate and inflamed area are the main qualities of the treatment. The creams are antiseptic against numerous microorganisms and do not irritate. Their action has a maximal effectiveness in pH 4-5.6, which is precisely the physiologic value of pH in the vagina as well as the pathological values of pH there.

For this reason a multi-parameter investigation was done with 275 women suffering clinically from vulvo-vaginitis, proven micro biologically, in order to determine the efficacy, lack of side effects and

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acceptance of the treatment for infections of the lower genitalia.

Patients: The investigation was conducted with women above 16 years of age with vulvo-vaginitis with various etiology (bacteria, fungi, parasites, etc.) with at least two of the following symptoms:

leukorrhea	
pruritus	
burning	
edema	
erythema	

Patients with the associated symptoms of the upper genitalia were excluded from the study.

Two hundred and seventy-five (275) patients were followed for a period of 9 months. The patients' ages varied from 16 to 62 years with a mean age of 32. More than 90% were younger than 45 years. In 71.6% of the cases the patients were using contraception, most often oral (44.40%) and intra-uterine (25.1%).

Lower genital pathology (vulvo-vaginitis) was the cause for consultation in 63.3% of the cases and 29.1% were regular patients in whom vulvo-vaginitis was diagnosed. A tendency of recurrence is seen in approximately 40.7% of women diagnosed with vulvo-vaginitis.

The initial diagnosis during investigation was:

candidiasis--83.9%

trichomonasis--7.3%

bacterial vaginosis--4.0%

chlamidia cervicitis--0.8%

herpes--0.8%

e-coli--0.8%

condyloma--0.8%

infected ectopia--0.8%

abscess of the left labia--0.8%

diagnosis of mycosis was confirmed in 76% of the cases and rejected in 24%.

The treatment with the antiseptic creams was carried out by a physician, who used the following technique of endocervical treatment:

With a speculum open the vagina. With swab, dry out and clean with the disinfecting solution. After that

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with a cotton swab, apply the cream of this invention to the whole vagina, including the cervix. After removing the speculum, apply cream also to the vulva. The treatment is not affected by the menstrual cycle.

Note: vaginal antiseptic creams will not replace etiologic treatment of the diseases of the vagina: they were applied in combination with the etiologic treatment. Creams were applied in combination with:

antimycotic locally--34%

antimycotic general application in combination with local application--7%

polyvalent wide spectrum local therapy--33%

trichomonadicide, general application--13%

oral antibiotics--3%

anti-virus--1%

Investigation consisted of three obligatory check-ups. The first check-up was done at the beginning of treatment (first day of the check-up)thorough clinical gynecologic check-up, obligatory microbiological investigation and competent endocervical sampling. The second check up (second endocervical sample) was carried out on the seventh day. The third check-up was done on the fourteenth day of the treatment. In cases of regression, without complete healing on the fourteenth day, a new application of the cream to the vagina was done.

The total effectiveness of the treatment was evaluated on the basis of the development of the clinical symptoms, which motivated the person to be included in the investigation: leukorrhea, pruritus, burning, edema and erythema. Each clinical symptom was evaluated on a degree from 0 to 3, according to the intensity during each check-up:

0--lack

1--of low importance

2--important

3--very important

The following of all symptoms during the check-up allowed following the clinical development of the process.

Each undesirable effect was noted on the evaluation sheet. It was presented during the second check-up. The sheet required the patient to evaluate the acceptance of the treatment as well as the development of the symptoms, general treatment and the vaginal cream in particular.

Two clinical symptoms are the main complaint during vulvo-vaginitis--leukorrhea and pruritus (FIG. 1). During the etiological treatment and the treatment with the 7.5% cream, most of the important symptoms (No. 2 and 3) disappeared on the second check-up on day 7 of the treatment (FIGS. 2 and 3). Results were evaluated on day 3, day 5 and day 7. These results were very significant. In 93% of the cases the patients were considered healed. That is the total result is less or equal on day 3, 5 and 7.

Development of the symptoms was evaluated each day by the patient up to the 7.sup.th day of the treatment, which allowed for assessment of the speed of improvement of the leukorrhea, pruritus and burning. Symptoms of the leukorrhea, pruritus and burning had almost disappeared by the 3.sup.rd - 4.sup.th day. See FIG. 4.

Vaginal creams with 5% and 7.5% Tribulus Terrestris L were very well accepted by 9 out of 10 patients. Acceptance was perceived as good in 85% of the cases and mediocre in 3.3% (FIG. 5). Subjectively, acceptance was considered good by 98.4% of the patients and bad by 2.4%. Thus, treatment continues in 98% of the cases.

Side effects reported were:

itching

slight irritation in the beginning

slight redness in the beginning

Overall vaginal creams could be considered well received in practice treatment. Again it was not the objective of this investigation to have the 7.5% cream replace treatment, but to use it in combination with etiologic treatment: i.e. antimycotic or polyvalent, local or general. In other words, the 7.5% cream is not used as the main treatment for diseases of the vagina but as an additional treatment with a dual role. Use of the creams results in: faster action on the functional symptoms (pruritus, burning, pain), local treatment against inflammation and infection of the vulva. The only inconvenience is that the treatment and endocervical sample should be carried out by a gynecologist, well qualified to treat the inflammatory diseases of women. Thus, local treatment is recommended.

In this study the qualities of the 7.5% cream were as follows:

efficacy--in 70% of the patients the leukorrhea was diminished and in 93% was

considered healed by the 7.sup.th day.

fast action, improvement of the functional symptoms even on the 3.sup.rd day.

acceptance-good in 87.7% of cases

lack of side effects during application in 98% of cases.

The use of the 7.5% cream was pleasurable to most of the patients (endocervical sample only once, rarely second time, by physician) and better than formerly used antiseptics in 39.6% of cases, where there was a former practice of application of antiseptic solutions and/or globules.

Two hundred and seventy-five (275) women with vulvo-vaginitis were treated with the 7.5% and 5% creams of this invention in combination with local or general treatment of the vagina. Most of the symptoms disappeared on the 3.sup.rd -5.sup.th day or on the 7.sup.th day. During this study the treatment of vulvo-vaginitis passed through two phases: adapted etiologic treatment, and additional local treatment of the vulva, which decreases the functional symptoms and benefits fight against infection.

Vaginal antiseptic creams in 7.5% and 5% strength with their efficacy, acceptance and lack of side

effects represent an additional local adapted treatment. This investigation was carried out in French Department Specialise Gynecologie Obstetrique Sofia, Bulgaria by Dr. B. Kirtchev.

The invention has been described with reference to particular embodiments. Other modifications and enhancements can be made without departing from the spirit and scope of the claims that follow.

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Tribulus Terrestris Update

Richard B. Kreider, PhD, FACSM

I recently came across a web site promoting the ergogenic value Tribulus terrestris. The site claimed that Tribulus supplementation would naturally boost testosterone levels leading to greater gains in muscle mass and strength during training. Is this true? This article discusses what we know and don't know about Tribulus terrestris so you can make an informed decision of whether to add this supplement to your training table.

Background

Tribulus terrestris is a plant (also known as puncture weed/vine or caltrops) that is mainly grown in sandy soil environments. It produces a fruit that is protected by a spiny burr. The extract from the fruit has been used in herbal medicine as a diuretic, for colic pains, and to fight hypertension and hypercholesterolemia (1,2). It has also been shown to increase testosterone levels (3) and improve sexual function in animals (3-5) as well as to reduce symptoms of angina pectoris in heart patients (6). Excessive intake of Tribulus terrestris has been reported to cause neuromuscular disorders in sheep (7-8).

The active agent in Tribulus is believed to be protodioscin. Protodioscin is a precursor to dehydroepiandrosterone (DHEA). As you may know, DHEA and androstenedione are precursors to testosterone. As one ages, androgen levels decline. Therefore, DHEA and androstenedione supplementation have been theorized as a means of naturally increasing testoserone levels particularly in older individuals. Although Tribulus is a precursor to DHEA, Tribulus is believed to indirectly affect testosterone levels by stimulating the release of leutinizing hormone (LH). LH serves to stimulate the natural production of testosterone. Theoretically, moderately increasing testosterone availability during training may promote greater gains in strength and muscle mass.

Does Tribulus Terrestris Work?

Well, as you know, the theoretical rationale behind many supplements sounds promising. However, the promises often fade when one looks at the scientific evidence supporting the theories. Tribulus is no exception. To date, there are only a handful of studies that have investigated the effects of Tribulus terrestris supplementation on hormone regulation, sexual function, health, and/or training adaptations. Most of these studies have been conducted in animals. Although several web sites claim that Tribulus terrestris supplementation markedly increases LH and testosterone levels, I was only able to find two published studies that have investigated the effects of Tribulus terrestris supplementation on training adaptations in humans.

In the first study, Antonio and colleagues (9) evaluated the effects of Tribulus terrestris supplementation during training on body composition and performance. In a double blind and randomized manner, 15 resistance-trained males ingested either 3.21 mg/kg/day of a placebo (P) or Tribulus terrestris (T) for eight weeks during a standardized resistance-training program. Prior to and following supplementation, subjects completed dietary inventories, a mood state psychological inventory, and had body composition (skinfolds and hydrostatic weighing) and total body water (bioelectrical impedance) measurements determined. The subjects also performed a maximum repetition tests on the bench press and leg press at

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100% and 200% of body weight, respectively. Results revealed that Tribulus terrestris supplementation had no significant effects on changes in mood states, total body weight (P +0.6, T +0.9 kg), total body water (P +0.9, T +0.3 liters), hydrostatically determined percent body fat (P +0.2, T +0.0 %), or gains in bench press (P +28.4, T +3.1 %) or leg press (P +26.1, T +28.6 %) muscle endurance. Although LH and testosterone levels were not assessed in this study, results indicated that Tribulus terrestris supplementation (approximately 250 mg/day) during resistance training had no significant effects on body composition or training adaptations.

Proponents of Tribulus terrestris supplementation have suggested that the dosage in the previous study may have been insufficient, that Tribulus terrestris may be more effective when coingested with other anabolic precursors, and/or that Tribulus terrestris may have a greater impact on untrained subjects initiating training. However, research findings from a study by Brown and associates (10) do not support these contentions. In the first part of this study, 10 subjects were evaluated to determine the effects of ingesting a placebo or anabolic precursors on hormone levels. Subjects had fasting blood determined and then ingested a placebo or a supplement containing 100 mg androstenedione, 50 mg DHEA, 250 mg Tribulus terrestris, 195 mg Chrysin, 100 mg Indole-3-carbinol, and 180 mg Saw palmetto. Blood samples were obtained every hour for six hours. Results revealed that anabolic precursor supplementation significantly increased androstenedione levels. However, no significant differences were between the placebo and anabolic precursor trials in LH, follicle stimulating hormone (FSH), estradiol, free testosterone, or total testosterone levels. These findings suggest that although anabolic precursors may increase androstenedione levels, they have no significant acute effect on other androgenic or estrogenic hormones.

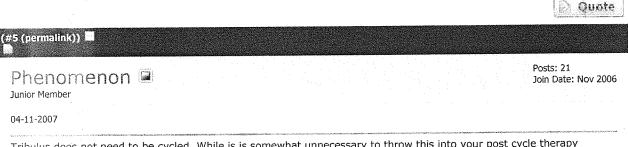
In the second phase of this study, 20 untrained young male subjects participated in a 3-day per week resistance training program for 8-weeks. In a double blind and randomized manner, subjects ingested a placebo (P) or a supplement containing 300 mg androstenedione, 150 mg DHEA, 750 mg Tribulus terrestris, 625 mg Chrysin, 300 mg Indole-3-carbinol, and 540 mg Saw palmetto (Andro-6) every day during weeks 1, 2, 4, 5, 7, and 8 of training. Fasting blood samples were obtained prior to supplementation and after 2, 5, and 8 weeks of supplementation. Body composition (via skinfolds and hydrostatic weighing) and one-repetition maximum (1RM) upper and lower body strength tests were determined at 0, 4, and 8 weeks of supplementation. In addition, muscle biopsies were obtained prior to and following the supplementation/training interventions to assess changes in muscle fiber diameter. Results revealed that chronic Andro-6 supplementation during training increased fasting androstenedione, estradiol, and estrone levels while decreasing high-density lipoproteins (HDL) levels. No significant differences were observed in LH, FSH, total testosterone, free testosterone, or estriol levels. Moreover, no significant differences were observed between groups in changes in body composition, muscle fiber diameter, or gains in 1RM strength. These findings suggest that ingesting Tribulus terrestris (750 mg/day) with other anabolic precursors does not significantly affect body composition or training adaptations.

Bottom Line

Despite popular claims, there currently appears to be little if any data supporting the ergogenic value of Tribulus terrestris supplementation for resistance-trained athletes. Additionally, studies that have evaluated the ergogenic value of other anabolic precursors in younger athletes have shown little to no benefit with some potentially dangerous side effects. My advice is to stay away from these types of anabolic precursors unless recommended by your physician.

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Tribulus does not need to be cycled. While is is somewhat unnecessary to throw this into your post cycle therapy because naolvadex and clomid and sometimes HCG will work all the wonders. In my opinion tribulus is a waste of money and I don't recommend anybody to buy tribulus because the benefit of supplementation versus cost of supplementations is far outweighed on the cost end. Its a rip off supplement marketed for increasing luteinizing hormone, testosterone, DHEA as well as estrogen.

A recent study found that 4 weeks of tribulus supplements (at 10-20 mg per kg body weight daily) did not affect male sex hormones testosterone, androstenedione, or luteinizing hormone compared to controls. This supplement is a fraud and does not have any unbiased research studies supporting its claim to increase chemical hormones into the body.

Although tribulus has become popular as a sports performance aid, one small but well-designed study found it has no effect on body composition or exercise performance. Fifteen subjects were randomly assigned to tribulus (3.21 mg per kg body weight daily) or placebo. After 8 weeks with resistance training, there were no changes in body weight, percentage fat, dietary intake, or mood in either group. What was surprising was that muscle endurance improved more in the placebo group! Muscle endurance (determined by the maximum number of repetitions at 100-200% of body weight) increased for the bench and leg presses in the placebo group. The tribulus group experienced an increase in leg press strength only.

The supplement is a rip-off. For some individuals, not the majority understand, they claim it is an aphrodisiac and that it does raise libido. This may be true but this may also be the placebo effect. The mind is powerful and can make yourself believe different phenomena. The mind can make a man preganant...look it up if you do not believe me....this is well documented. The man actually lactated like a female while not having female organs and his estrogen levels spiked sky high. The brain is powerful and you can trick yourself beleieving a supplement works when really your training hard and doing well with a placebo effect. Tribulus is a clever marketing scam period.

If you were to buy a tribulus product which I do not recommend, buy a product called Viraloid

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